REMARKS

Claims 1 and 4-16 are pending. Claim 1 is amended in response to the Examiner's rejection and to further clarify the claim. The amendment is supported, without limitation, at paragraphs 20-24, 50-57, 63-76, 85-91 and Figures 2, 3 and 5 of the specification. No new matter is added. Based upon this amendment, and the remarks below, Applicants request that the Examiner reconsider and withdraw the rejection of the pending claims made in the Office Action dated February 9, 2009.

Silence with regard to any of the Examiner's rejections is not acquiescence to such rejections, but rather a recognition by Applicants that such previously lodged rejection is moot based on Applicants' remarks and/or amendments. Specifically, silence with regard to Examiner's rejection of a dependent claim, when such claim depends from an independent claim that Applicants consider allowable for reasons provided herein, is not an acquiescence to such rejection of the dependent claim, but rather a recognition by Applicants that such previously lodged rejection is moot based on Applicants' remarks and/or amendments relative to the independent claim (that Applicants consider allowable) from which the dependent claim depends.

Section 101 Rejection

The Examiner rejected claims 1 and 4-16 under § 101 as being directed at non-statutory subject matter. In particular, the Examiner stated that the claims were neither tied to a particular machine or apparatus, nor transformed a particular article into a different state or thing. In addition, the Examiner stated that there was no real world application, as the methods could take place entirely within a computer.

Applicants suggest that claim 1, as amended, is directed at statutory subject matter, and cannot take place exclusively in a computer. First of all, the claim step "based on the surgical plan, disposing the one or more fixators on the bone" transforms a particular real-world article into a different state. Nor can that step be considered merely insignificant extra-solution activity, because it is followed by other steps, at least one of which further transforms a particular real-world article into a different state, namely the

steps of "based on data associated with the placement of the one or more fixators disposed on the bone… generating …an updated surgical plan including updated settings for one or more of the one or more struts; outputting the updated surgical plan …; and based on the updated surgical plan, adjusting at least one setting of a strut of at least one fixator." This, by itself, demonstrates that amended claim 1 is directed at statutory subject matter.

There is a second reason claim 1 is directed at statutory subject matter. As amended, claim 1 is carried out "[u]tilizing a computer system comprising at least one input device, at least one output device, at least one storage device, and at least one suitably-programmed computer." Moreover, the "three dimensional (3D) model of the bone" is generated "in at least one suitably programmed computer." In addition, "the … 2D images [are] input into the computer system by means of at least one input device," the "3D bone template" is "chosen from a set of 3D bone templates stored in at least one storage device," the "surgical plan" is generated "in at least one suitably-programmed computer," the "surgical plan" is output "by means of at least one output device," the "data" is "input into the computer system by means of at least one input device," the "updated surgical plan" is generated "in at least one suitably-programmed computer," and the "updated surgical plan" is output "by means of at least one output device."

As demonstrated above, this amendment adds no new matter. Applicants respectfully submit that this amendment renders claim 1 patentable subject matter, in that as amended it is tied to a particular apparatus, as *Bilski* suggests suffices for Section 101 patentable subject matter, and is not merely "mental steps" or steps which can take place exclusively within a computer. In particular, the methods of this amended claim, including the inventive steps, are performed on a computer system containing at least one input device, at least one output device, at least one storage device and at least one computer. Moreover, the computer(s) must have been "suitably programmed" to carry out the claimed method, and thus are not merely one or more general-purpose computers.

Respectfully, Applicants suggest that this amendment responds fully to Examiner's rejection, and that, as amended, claim 1 is patentable subject matter.

Insofar as claim 1 is patentable subject matter, it follows that claims 4-16, which depend from claim 1, also are patentable subject matter.

<u>Section 103 Rejection</u>

The Examiner rejected claims 1, 2 and 4-16 under Section 103(a) as being unpatentable over Fleute et al ("Nonrigid 3-D/2-D Registration of Images Using Statistical Models"), in view of DiGioia et al ("Computer Assisted Orthopedic Surgery. Image Guided and Robotic Assistive Technologies") and Background art (specification, p. 4).

The Examiner cited Fleute for teaching an "algorithm for generation of [a] three dimensional model of a bone by reconstruction of 3D shapes using x-ray views and a statistical model." The Examiner further stated that "the "3-D model of the patient bones is constructed [in Fleute] by deforming a statistical 3-D model to the contours segmented on the x-ray views. The statistical model (template) is made of a few principal modes that are sufficient to represent the *normal* anatomy." (Office Action, p. 5) (Emphasis added.)

In response, Applicants have amended claim 1 to provide that the three dimensional (3D) model of the bone is generated based on one or more two dimensional (2D) images of the bone and "a 3D bone template, chosen from a set of 3D bone templates stored in at least one storage device, *to which a free form deformation is applied.*" (Emphasis added.)

Respectfully, Applicants suggest that Fleute does not teach claim 1 as amended, at least for the following reasons. As the Examiner notes, in Fleute the patient's bone is modeled based upon x-rays of the patient and a single statistical model of a *normal* bone. In particular, in Fleute, as cited above, the assumption is made in applying the statistical model that "a few principal modes … are sufficient to represent the *normal* anatomy." Therefore, the patient bone is approximated only by adjusting the coefficients of the

limited number of principal modes in the single statistical model. As Fleute explicitly recognizes, however, this approach has its limitations; it works best for "normal" bones but, as Fleute states, "[w]hen dealing with pathological shape deformations which are not covered by the statistical model, local refinements of the model are necessary to obtain a sufficient good fit between the model and the projective data." (Fleute, p. 146) Fleute does not spell out what these *ad hoc* "local refinements" are, or how they are carried out, but the point is clear: the method described by Fleute based on a statistical model fails on bones that are not "normal."

Claim 1 as amended, in contrast, does not use a single "statistical model" of a bone which restricts variations in patient bone shape to those constructed from a limited number of preselected "principal modes." Rather, in claim 1 the template to use as the starting point for modeling the patient's bone *is selected from a set of templates.* This alone distinguishes claim 1 from Fleute. Then, rather than being limited as in Fleute to modifications expressed as coefficients of "principal modes," claim 1 permits "free form deformations" to be applied. An advantage of free form deformations is that they are not restricted to modeling "normal bones" as is the case with Fleute. This is important because the process of claim 1 is designed to assist in bone distraction, and bone distraction frequently may be required in a case when a bone is *abnormal* rather than normal – in order to correct the abnormality. In such a situation, a method such as Fleute's which is based upon and limited to "normal" bones and predetermined modes of variations therefrom is of limited utility. It follows that Fleute does not teach the limitation of amended claim 1, that the three dimensional (3D) model of the bone is generated based on one or more two dimensional (2D) images of the bone and "a 3D bone template, chosen from a set of 3D bone templates stored in at least one storage device, to which a free form deformation is applied." Insofar as the Examiner does not suggest that DiGioia teaches this limitation, it follows that claim 1 is allowable over Fleute and DiGioia.

Claim 2 was previously canceled.

Claims 4-16 depend from claim 1. Insofar as claim 1 is allowable for the reasons set forth above over the above-cited art, claims 4-16 also are allowable.

The Examiner further rejected claims 1 and 4-16 under Section 103(a) as being unpatentable over D'Urso (U.S. Patent 6,112,109), in view of DiGioia et al ("Computer Assisted Orthopedic Surgery. Image Guided and Robotic Assistive Technologies") and Background art (specification, p. 4), and further in view of Fleute et al ("Nonrigid 3-D/2-D Registration of Images Using Statistical Models").

In this rejection, the Examiner acknowledged that "D'Urso does not teach use of 3D bone templates in reconstructing 3D data set." (Office Action, p. 9) Nor did the Examiner suggest that DiGioia taught that limitation. Rather, the Examiner asserted, using the same language as in the rejection discussed above, that Fleute taught this limitation. (Office Action, p. 9) However, Applicants have demonstrated above that Fleute does not teach the limitation of claim 1, as amended, that the three dimensional (3D) model of the bone is generated based on one or more two dimensional (2D) images of the bone and "a 3D bone template, chosen from a set of 3D bone templates stored in at least one storage device, to which *a free form deformation is applied*." It follows that claim 1 is allowable over D'Urso in view of DiGioia et al and Background art (specification, p. 4), and further in view of Fleute.

Claims 4-16 depend from claim 1. Insofar as claim 1 is allowable for the reasons set forth above over the above-cited art, claims 4-16 also are allowable.

CONCLUSION

Applicants submit that the pending claims are now in condition for allowance, and request such action.

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The Commissioner is hereby authorized to charge an extension fee, together with any further amount required for proper filing of this paper, to our Deposit Account No. 06-1448, Reference CMV-005.03.

Applicants invite the Examiner to contact the Applicants' Attorney if questions arise regarding this Response.

Respectfully submitted,

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